## **NWX HHS FDA**

Moderator: Irene Aihie October 20, 2014 11:14 am CT

Coordinator: I'd like to thank all participants for holding. All lines will be on listen-only

until the question-and-answer portion of today's conference. I'd also like to

inform participants today's call is being recorded.

I'd now like to turn the call over to Irene Aihie. Thank you. You may begin.

Irene Aihie: Thank you. Hello and welcome to today's FDA Webinar. I am Irene Aihie, of

CDRH's Office of Communication and Education.

Today we will be discussing the guidance document, Custom Device Exemption which was published on September 24. The guidance is intended to clarify exemptions for custom device manufacturers by defining terms and explaining requirements.

Today you will hear from two presenters: Erin Keith, Director of the Division of Anesthesia, General Hospital Respiratory, Infection Control and Dental Devices and CDRH's Office of Device Evaluation and Leslie Caster, Consumer Safety Officer in the Division of Premarket Labeling Compliance

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and CDRH's Office of Compliance. Erin and Leslie will present an overview of the guidance document and then we'll open the lines to take your questions.

Following today's Webinar the slide presentation, audio recording and written transcript of today's program will be available on the CDRH Learn section of the FDA website.

Now I give you Erin.

Erin Keith:

So good afternoon, everybody, and thank you for participating in today's Webinar where we're going to discuss the customer device exemption guidance document. Today's Webinar is going to be divided into the two main topics covered in the custom device exemption guidance document. Those are some policy - the policy which is related to custom device exemption and the annual report requirement. I'm going to present the information on the policy portion of the Webinar and Leslie Caster will be presenting the information on the annual report requirements.

The main purpose of my presentation is to orient you to what is contained in the policy section of the guidance document. But before we get to the guidance document itself I want to describe a little history of the custom device exemption itself, the current - and the current version of the exemption.

The original version of the exemption was contained in the 1976 medical device amendment. It was a very narrow exemption from premarket requirements where a series of conditions were required to be met in order for a device to be considered a custom device. The interpretation of that particular provision was it was a one-off for a single new device, not a customization of an existing device.

I'm notified that there's an error in relationship to the FDASIA date. It should be July 2012, not July 2014.

In July of 2012 the Food and Drug Act was amended under the FDASIA Act where the custom device exemption was expanded. While it is still narrow and a series of conditions must be met it was expanded from its extremely narrow one-off from the original. It also added a new requirement for industry related to annual reports.

For those of you who have not seen the current version of the custom device exemption I wanted to walk you through the clauses and the sub-clauses for the current version of the law. The current version of the law requires that all of the parts, A through G, of B1 and all of the parts, A through C, of B2 of 520(b) are met in order for a device to be considered a valid custom device.

The provision states that in general the requirements for Section 514 and 515 shall not apply to a device that is created or modified in order to comply with the order of an individual physician or dentist in order to comply with an order prescribed in Paragraph A necessarily deviates from otherwise applicable performance standards under Section 514 or the requirements under Section 515.

It is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer or distributor for commercial distribution. It is designed to treat unique pathology or physiological condition that no other device is domestically available to treat. It is intended either to meet the special needs of such a physician or dentist in the course of his or her professional practice or is intended for use by an individual named in such order of such a physician or dentist.

It can be assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of the individuals prescribed in the Clause 1 and 2 of Sub-Paragraph E. It may have common, standardized design characteristics, chemical and material compositions and manufacturing processes as commercially distributed devices.

I just want to note two things, that clause - Sub-Clause E1 and E2 describe two potential options for the custom device. One is physician-focused or physician-centric. And the other is patient-focused or patient-centric. And then additionally Clauses F and G expand or broaden the devices that can qualify as a custom device by allowing for changes in similarities in manufacturing.

In addition, the custom device have to also meet the limitations described in five - in (20BU), Parts A through B. This is - states that Paragraph 1 shall apply to a device only if such device is for the purpose of treating a sufficiently rare condition such that conducting clinical observations on such a device would be impractical. Production of such a device under Paragraph 1 is limited to no more than five units per year of a particular device type, provided that such replication otherwise complies with this section and finally the manufacturer of such device notifies the agency on an annual basis of the manufacture of such devices.

There are some really important changes under the FDASIA version of the custom device exemption that I want to highlight, the first being that those new and modified existing devices have the potential to qualify for the custom device exemption.

There is the potential for multiple units of a device type in a - in one year, no more than five per year. There is also an additional annual report - reporting

requirement for the manufacturer. And Congress has told us the issued guidance document addressing how we would deal with the replication of units of no more than five, in other words how we would count to five.

So the guidance document, as I stated before, is divided into two primary sections. One covers policy. And the other covers the annual report.

In the policy section we provide definitions that are important for the implementation of the custom device exemption, explain how we propose - how we are going to count to five for the replication of up to five - of - not to include - of five units a year. And we also address some common custom device exemption questions that the agency has received over the years.

The annual report section addresses the general content and the logistics of submission and provides specific information to submit for the patient-centric custom device and specific information for the physician-centric custom device.

In the policy section there are three main portions of the policy section. The first one deals with key definitions. These definitions - the definition section addresses key terms important to implementing the custom device exemption. Wherever possible the terms are based on existing CDR definitions or are linked to the language in the law.

Some of the - I've listed some of the key definitions in this slide. However as an example in the guidance document device types is defined as - a generic device type is defined as a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function or any other feature related to safety and effectiveness for which similar regulatory controls are

sufficient to provide reasonable assurance of safety and effectiveness. This

definition comes from 21 CFR Part 860.3(i).

Some of the other key definitions that are included in the document are necessarily deviates, not generally available, special needs, sufficiently rare

condition, unique pathology, unique physiological condition.

The next portion of the policy section of the guidance document addresses the

replication of five units a year. The law limits to no more than five units of a

device type per year. And it directed FDA to issue this specific guidance

document.

FDA interprets five units in terms of five new custom devices per year in five

new patients for a patient-focused device or five new physicians for a

physician-focused device, assuming that all other required elements for the

custom device exemption are satisfied.

The five-unit limitation includes all devices of a device type provided to -

provided by a manufacturer to and remaining in the possession of the ordering

physician or the patient. However we are a - the guidance document allows for

count - allows for sizing. FDA does not intend to include in the tally of five

units per year any extra units produced for a unique case because of sizing

concerns so long as the ordering physician has neither destroyed those devices

not used for that case or they have returned them to the manufacturer and the

devices are not redistributed without a valid U.S. marketing authorization or a

subsequent valid custom device case.

The final portion of the policy section deals with common custom device

exemption questions that we have received over the years. For example the

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first question in the guidance document is from - states from which premarket

and post-market requirements is my custom device exempt?

And the answer contained in the guidance document reads: under Section

520(b) of the FD&C act custom devices are exempt from premarket approval

requirements and conformance to mandatory performance standards. Custom

devices are not exempt from any other regulations including but not limited to

the quality system regulation including design controls, medical device

reporting, labeling, corrections and removal and registration and listing.

I've listed some of the questions that you will find in the guidance document.

This is not an exhaustive list. But some of the other questions include: can a

device be subject to an IDE, be a custom device; can a custom device be both

a physician-centric and a patient-centric device; can modifications to a 510(k)

device qualify as a custom device; how are revisions and servicing of existing

custom devices included in the limit of no more than five of a device type per

year; how to label a custom device and examples of what is and what is not a

valid custom device?

At this point I'm going to turn the presentation over to Leslie and she will

discuss the annual report section of the guidance document.

Leslie Caster:

Good afternoon. As Erin said, I'm going to discuss the annual report section.

Due to the statutory amendments in FDASIA to the custom device exemption

manufacturers are now required to submit annual reports. The manufacturer of

a custom device must report to FDA annually on the custom devices it has

supplied.

The annual report should cover an entire calendar year and be submitted to FDA within the first quarter of the following calendar year no later than March 31. This first year's reports are due on March 31, 2015 and should cover the period from July 9, 2012 when FDASIA was enacted through December 31, 2014.

Information that should be included in the annual report is the number of all custom devices distributed and account for custom devices that were returned or destroyed and the number of patients who received a device or revisions of a previous custom device. If multiple custom devices were used in one patient each custom device used must be accounted for in the annual report.

A cover letter should accompany the annual report and contain the following: a reference line that states custom device annual report, contact information, the number of custom devices manufactured and distributed and the reporting period. The annual report must also contain a truthful and accurate statement.

We recommend you use the language provided here on this slide. This language is also provided in the appendix - in Appendix 2 of the guidance.

As Erin mentioned earlier custom devices are either patient-centric or physician-centric. The next few slides will address patient-centric custom devices and the justification required for how or why the device manufactured to treat an individual patient meets the following conditions contained in the Food, Drug and Cosmetic Act. Please refer to the guidance document for this information with respect to physician-centric custom devices.

For Sections 520(b)(1)(B) and 520(b)(2)(A) explain why the device necessarily deviates from the premarket requirements including treating a sufficiently rare condition such that conducting clinical investigations aren't

practical. You may include information on the incidence or prevalence of the condition or disease the device is intended to diagnose, treat, mitigate or prevent. In addition you should include an explanation of why conducting clinical investigations on such a device would be impractical.

For Section 520(b)(1)(A) indicate whether the device is a newly created device or modified from an existing legally marketed device in order to comply with the order of an individual physician. For Section 520(e)(1)(C), a test that the device is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer or distributor for commercial distribution.

For Section 520(b)(1)(D) and 520(b)(2)(B) provide a complete description of the device including device type -- for example the product code -- and the patient's unique pathology or physiological condition that the device was designed to treat. To show that Section 520(b)(1)(D) is met provide a statement that no other devices domestically available to treat the patient's unique pathology or physiological condition. You should maintain records of the evaluation that you used to determine that no other device is domestically available to treat the patient's unique pathology or physiological condition.

For Section 520(b)(1)(E)(2) provide a unique patient identifier for the individual patient in the physician's order.

For Section 520(b)(1)(F) state whether the device is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals. In addition, for Section 520(b)(1)(G) explain whether the device or device components have common standardized design characteristics, chemical and material compositions and the same manufacturing processes as commercially distributed devices.

When submitting annual reports to FDA custom device manufacturers submit

- should submit two copies of the annual report including at least one hard

copy to the address contained in the guidance document. For those of you who

may have printed the document prior to last week please note that the room

number for the annual report submission has changed and is now Room 2622.

But the rest of the address is correct.

Although it is not required it is strongly encouraged that one of the two copies

be submitted as an e-copy, for example a PDF file on a CD, DVD or flash

drive. For more information about submitting an e-copy please refer to the

guidance document titled E-Copy Program for Medical Device Submissions:

Guidance for Industry and Food and Drug Administration Staff. The link for

this document is provided in the custom device exemption guidance document

also.

How will FDA use the information we obtain from annual reports? Well first

off the information will help FDA understand how industry is interpreting and

applying the custom device exemption and can shed light on areas that may

need further clarification.

Annual reports will also allow FDA to ensure compliance with the custom

device exemption. Primarily it will allow us to know if industry is

manufacturing and distributing only the permitted number of custom devices

per device type per year as defined in FDASIA and explained in the guidance.

In addition FDA will use the information to track the number and types of

custom devices, to respond to inquiries from stakeholders such as Congress.

What if FDA determines that a device distributed did not meet the requirements of the exemption? The FDA's primary focus is helping manufacturers implement the custom device exemption correctly and efficiently. The FDA intends to notify a manufacturer in writing about the reasons the devices are not eligible for the exemption.

The FDA will consider taking enforcement actions when the situation calls for it. But if upon our review of the annual report we determine that a company manufactured and distributed devices not eligible for this provision we do not generally intend to use enforcement actions to inform the company. Rather, the FDA intends to notify the company in writing about the reasons that the devices were not eligible for the exemption with the expectation that such clarifications will prevent future incorrect application of the exemption. The FDA may consider enforcement action for a company that manufactures and distributes devices under this provision that are clearly not eligible or have been previously notified by the FDA that they are not eligible.

And that concludes my portion.

Irene Aihie: We'd like to open the line up for questions.

Coordinator: Okay. At this time if you would like to ask a question press Star 1. Please record your name when prompted. Once again that's Star 1 to ask a question.

One moment for our first question. (Lauren Camer), your line is open.

(Lauren Camer): Hello. In terms of the custom device exemption the guidance clarifies that custom devices are not exempt from registration and listing requirements.

However when I've gone into FURLS to take a look at how that would occur if you enter a pro code that, say, is a Class 2 device it automatically yells at

me if I don't supply it with a 510(k) number. So I'm just wondering logistically how do we go about listing custom devices in FURLS?

Eric Horowitz:

Hello. This is Eric Horowitz. And currently the quality system working group (unintelligible) a lot of input on the custom device guidance.

So the question you're asking is a good question. The logistics of how it's - how custom devices should be registered and listed are a better question for the registration and listing staff. They should be able to direct you about how to go about registering and listing custom devices.

But it shouldn't - there should be good ways of doing that. It shouldn't end up being a burden. We certainly will - if there are changes that need to be made in order to facilitate the process, then you may have to work with the registration or update that to ensure that that's true.

(Erin Keith):

Hi, this is (Erin Keith). Yes, the point that I would make about that is that it is possible.

We do have pro-codes for devices that do not have clearances. So to correlate to devices that do have clearances that relate to devices that are manufactured for export only.

So my sub-position is that if you would be using those product codes verses the product codes that would go through either the 5-10K or any of the premarket programs.

Coordinator:

Okay, our next question is from (Julie). Your line is open. Once again, (Julie) your line is open.

Okay, we'll move on. (Patricia) your line is open.

(Patricia Dairy): Yes, my name is (Patricia Dairy). I have a newly approved patent for a device

- - Brain Paths.

I got an email to attend this conference - - telephone conference. I'm not sure

if my device qualifies.

I need to talk to somebody about that. Who would I talk to?

(Erin Keith): So you would. This is (Erin Keith). You would want to talk to the office of

compliance in (Leslie)'s division. So (Leslie) can give you a contact.

(Patricia Dairy): (Leslie).

Erin: Yes, if you can contact the custom device exemption mailbox, the email

address is customdevices@fda.hhs.gov.

For any questions you can just send it to that mailbox. And we'll get back to

you.

(Patricia Dairy): Is custom device - could...

Woman: Custom devices with a S.

(Patricia Dairy): Okay.

Woman: @fda.hhs.gov.

(Patricia Dairy): Thank you very much.

Woman: Yes.

Coordinator: Okay, we'll take our next question. (Kim Isagary) your line is open.

(Kim Isagary): I have a question about owner/operator numbers verses registration numbers

for a device. I have a factory that has an owner/operator number but not a

registration number yet.

Can I bring the product in to the U.S. without his registration number? And

how do I add him to my importers registration without his registration

number?

Man: I think that would be a question better asked of the registration enlisting staff.

I don't think your question is necessarily specific to custom devices.

The requirements for registration enlisting shouldn't be any different for a

custom device - verses any other device.

(Kim Isagary): Okay. So I'll contact them because I have a device that we're bringing in. But

the factories haven't received their registration numbers yet - just their

owner/operator numbers.

And I was wondering if I could. When they bring them in, if I just submit

owner/operator number - if that's enough information to bring them into the

U.S.

Man: Again, I would contact the registration enlisting staff. They should be able to

answer your question.

Woman: So, and the registration enlisting staff can be reached at reglist@cdrh.fda.gov.

They have a helpdesk phone number. That is 301-796-7400.

(Kim Isagary): Thank you.

Coordinator: Okay. Next question from (Stephanie). Your line is open.

(Stephanie): Hi I have a question about when the first annual report is due. Because when I

read the guidance document, there was a statement in there.

And it said, "FDA will not enforce the annual reporting requirement until the

end of the calendar year - following publication of the final guidance."

And I interpreted that to mean it wasn't going to be enforced until the end of

2015. But it sounds like you're saying you want the first one in March of

2015.

Woman: Could you repeat that? You broke up quite a bit on our end. And we didn't

quite catch your whole question.

(Stephanie): I was wondering about when the first annual reporting's due. And there's a

statement in the guidance document itself.

That says, "FDA will not enforce the annual reporting requirement until the

end of the calendar year - following publication of the final guidance."

(Leslie Caster): Right, so this is (Leslie Caster). The first annual report is going to be due the

first quarter of the calendar year - so between January and March 31.

(Stephanie): So you want it in March of 2015 because I interpreted this as the year

following it.

(Leslie Caster): Right. Yes, 2015.

(Stephanie): I interpreted that as it wouldn't be enforced until the end of 2015 and

therefore, not due until 2016. But that is not what was intended

(unintelligible)?

(Leslie Caster): No.

(Stephanie): Okay.

(Leslie Caster): No, the guidance weren't finally this year in September.

(Stephanie): Right.

(Leslie Caster): So it was the end of this year of 2014. So therefore, the reports are due the

first quarter.

Woman: Because after a year - in which the publication of the final guidance occurred

not the year following the publication.

(Leslie Caster): Right.

(Stephanie): Okay.

Man: Yes, to be clear, the language in the guidance I think intended to refer to the

following year.

(Stephanie): Okay.

Man: It's intending to refer to following the issuance of the guidance.

(Stephanie): Okay. That's good. I just didn't know that.

Coordinator: Okay. Next question from (Linda). Your line is open.

(Linda): Hi, the guidance document states that there is a tracking requirement. So you

talked about different sizes of devices that may have been shipped out.

You know, how will the FDA be handling these? As we're going back a few

years, this information may not be available in every circumstance about the

return of the product.

So how will FDA be handling that when you receive the annual reports?

Woman: So I would say that our expectation would be for you to make your best effort

to provide all of the information in the first report - that we are asking for.

But we realize that it's coming out in September. And it's six months,

basically, until it's due. So make your best effort to provide all the

information.

And then plan to move forward for the next year to have a more complete set

of information.

Woman: Okay. Thank you.

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Coordinator:

Before we take our next question, once again Star 1 to ask to question. And you must record your name when prompted.

And our next questions from (Ian). Your line is open.

(Ian):

Hello. My question relates to physician centric custom instruments. I'm curious as to whether that would apply to instruments that are modified versions of existing devices - perhaps for a surgeon to attempt a different approach.

Woman:

So the physician centric device is intended to address physicians' specific need in his or her practice. Associated with an anatomical need associated in order to practice medicine and use that particular device.

It's not related to a specific changing of surgical technique and approach. The physician centric device has been hard for us to provide good examples.

Because no one has ever actually provided us with one on how they saw implementing that particular part of the exemption.

But the first part of your question - but yes, modification to existing devices is potentially possible under the custom device exemption. Even for the physician centric if it's all of the other requirements of the exemption.

(Ian): Okay. I understand. Thank you.

Coordinator: Our next question comes from...

Recording: (Cheryl Selmer).

Coordinator: Your line is open.

(Cheryl Selmer): Hi, this is (Cheryl Selmer). I was just wondering if you could repeat the email

address for help with registration enlisting.

Woman: Yes. Just give us a minute to get that again. Okay. That would be the email

address is reglist@cvrh.fda.gov. And their phone number is 301-796-7400.

(Cheryl Selmer): Great. Thank you.

Coordinator: Next question from (Bradly). Your line is open.

(Bradly): Hi, I have two questions regarding device type and the limit of five. In the

guidance it says that knee replacement devices and must compromise multiple

device types.

I'm assuming this would be such as a femoral component or tibial component.

Does the guidance allow for up to - or no more than five units of a femoral

component and separately five of a tibial component?

(Erin Keith): Hi, this (Erin Keith). And the portion of the guidance document isn't referring

to the components that make up a device type.

It's referring to the 23/24 product codes. We have that defined that many

different device types that are in the knee replacement systems.

So it's not going down to the component level, it's going down to the device

type level.

((Crosstalk))

(Bradly): So in this case you're saying that a...

((Crosstalk))

(Erin Keith): So for example of (U-knee) - the difference between a (poly knee) - a (U-

knee) on a metal on metal (U-knee) (unintelligible) - the metal on (poly) -

total knee - a constrained knee versus a semi constrained knee.

Those are the ways that we categorize different device types with different

characteristics for (knee) systems.

(Bradly): But not at the component level in terms of a patient...

(Erin Keith): Correct.

(Bradly): ...only needed the tibial component or only needed a femoral component.

Those would still just be considered a knee component.

(Erin Keith): Correct.

(Bradly): Okay. And then the second question had to deal with the disease state. It says

- again, along the same lines could be used in different disease states can

constitute different device types of knee systems.

So does this mean that if there was - provided all the other requirements for

custom device were met? That if this particular disease state - there were two

particular disease states that each constituted, you know, sufficiently rare

conditions.

That you could do five to treat one disease state and five to treat a different disease state of both being a knee component.

(Erin Keith): Yes. So we have - we use indications for use of part of the way that we define

device types. And so if that is a - that's potentially a dividing line for device

type.

(Bradly): Okay. Thank you.

Coordinator: Next question from (Mark). Your line is open.

(Mark Bradwin): Thank you, (Mark Bradwin) here. Quick question, could you clarify the way

that the FDA is going to record or count the devices that are returned to the

company? (Unintelligible) and then left with the patient or the physician.

Woman: So devices that are returned to the company will not count in the overall side,

per year of five units of a given device type, per year.

(Mark Bradwin): So if we're building a device for a short term or temporary condition, then that

- then it's returned us. So would not be counted - is that correct?

Woman: No. I'm not. I think you would have to be more specific about what that

specific short term temporary situation is. Device went and was used by that

patient and it's for that doctor and it fulfilled that need.

So that would be one use. But if you were making sizing options - so you

didn't know exactly the correct size and would only know that at the time of

surgery. So you covered your basis with your patient.

And have a range of sizes that would be available to the doctor to use. Then those that are not used for that case and are either destroyed by the physician. And they provide you with that statement.

Or are returned to the company, would not count in the five units that were distributed that year.

(Mark Bradwin): Thank you very much.

Coordinator: Okay. Next question from (Bill). Your line is open. Please check your mute

button. (Bill), your line is open.

(Phil Gibbs): Yes, hello, this is (Phil Gibbs) - a few quick detail questions. As far as the

labeling of patient identification and surgeon identification, do you have any

guidance on how best to do that?

I mean is it as simple as, you know, such as first initial, last name of the

patient or what? Do you have any guidance in that regard?

Woman: We're leaving a little open to you to decide what's appropriate. We don't want

to put anybody in a situation where they would be violating confidentiality

rules - that other government agencies have about healthcare.

And provide us with names that they shouldn't be providing to us. So it's

initials, numbering, dating; however it works for you.

(Phil Gibbs): And is the terminology "custom made device" acceptable on the label. So that

it kind of marries up with the European regulations.

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Woman:

I can't answer that question. The person from the office of compliance who would be able to answer that isn't here.

Could you send us that question to the address on the last slide at Dice? And we'll get you an answer.

(Phil Gibbs):

Okay. Also, in the tables - if you could - on table one in the summary type table. You've got a couple of columns.

One is custom device identification. And the second column is product code. I'm a little confused, still, on this, you know, the difference between device type and product code.

Could you talk about that a little bit? What do you want in each of those columns? And are we working off of product code or device type?

Because I thought there was a distinct break from product code when I read through this document.

Woman:

So I would. I'll let (Leslie) add anything that she wants to after this.

I would say that the device type would be how you are defining the device and how you have categorized it according to the definition that's in the regulations and included in this guidance document.

Product code is included in a case that you have modified an existing device. And you would like to know which device it was that was modified.

(Phil Gibbs):

Okay. So what type of data are you looking for in the first column - - custom device identification. Is that - would device type be appropriate there?

Man:

So that first column isn't about identifying device type. It's intended to be an identification of the individual custom device.

So if you have some sort of identifier of what that device is. The concept is that you're identifying each device individually.

(Phil Gibbs):

Okay. I'm just trying to get to, you know, how do we differentiate out the five in this table? I guess is what I'm trying to drive at.

I'm not seeing. And I thought I was summarizing or would be summarizing, you know, the quantities of each device type that we did in a year. I hope that question's clear.

Coordinator:

Okay. Next question from (Allison). Your line is open.

(Allison):

Hi you state that in your guidance document that we should maintain records of the evaluation that we used to determine that no other device is domestically available to treat that patient.

You need pathology or physiological condition. How does the FDA intent to have a manufacturer provide proof of a patient unique pathology, if that instances or prevalence is so small?

That conducting a clinical investigation is considered impractical. We can only provide, you know, research and references to the best of our knowledge.

Woman:

Well just as you said, what you can provide us is fine. Let me. I'm going to pass this on to (Eric).

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(Eric):

So the expectation there - as you said - there isn't always going to be perfect information on every single one of these instances.

And our expectation is that you have reasonable information - that you've put a good faith effort into getting all the information that you can in order to make a determination.

That no other device is domestically available to treat that condition - so we understand that the amount of information that will be available for that evaluation will vary.

So, yes we understand those kinds of situations. It's not like we're going to treat every single situation like everyone is going to be able to get the same information.

(Erin Keith):

And also say that this (Erin). That we recognize you can't, you know, prove the negative.

And the expectation is that the company makes a reasonable good faith effort to ascertain whether or not there's something domestically available for that particular situation.

And that you document what you did to make that determination.

Woman: Operator, are there any more questions?

Coordinator: Showing no further questions.

(Irene): Well thank you. This is Irene Aihie. And we appreciate your participation and questions today.

Please remember that this presentation will be available on the CDRH Learn

section of FDA.gov - under the heading, "Specialty Technical Topics."

The written transcript and recording will be available on Monday, October 20.

If you have additional questions, please use the contact information provided

at the end of the slide presentation.

As always, we appreciate your feedback on today's presentation. Again, thank

you for your participation. And this concludes today's Webinar.

Coordinator: Okay. Thank you. Once again, that does conclude the call for today. You may

disconnect your phone lines at this time.

**END**